

# CLINICAL PHARMACOLOGY and THERAPEUTICS

volume 27 number 4

April, 1980

## Commentary

### Informed consent: How much does the patient understand?

*Comprehension and recall of the information contained in the informed consent statement was tested in clinically hypertensive patients entering a controlled trial comparing hydrochlorothiazide and propranolol. The consent statement was the primary vehicle for conveying the information to the patient. The average of correct answers to a multiple-choice quiz was 71.6% at 2 hr and 61.2% at 3 mo after the consent procedure. The effectiveness of recall did not correlate with level of education. Patients exhibited greater comprehension of the action of the drugs than of their side effects. Nearly all patients indicated their belief that they would receive the best possible care. While 95% wanted to be informed about the trial, 75% stated they would have given their consent even without this information.*

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An important and still unanswered question concerning informed consent is how well the patient comprehends the nature of the investigation and his or her role in it. The prevailing opinion seems to be that the information is poorly assimilated by the patient.<sup>2, 5</sup> Many factors influence the patients ability to understand the content of informed consent. Obvious factors include the complexity of the design of the

trial, the clarity with which the relevant material is presented, and the curiosity and intelligence of the patient. How well do patients understand the type of drugs used, their possible side effects, the special tests that will be required, and the basic design and duration of the trial? Our study was designed to provide data on these questions, both with respect to immediate recall as well as late recall 3 mo after informed consent had been obtained.

#### Methods

The investigation was carried out with patients entering a Veteran's Administration Co-

Received for publication Oct. 29, 1979.

Accepted for publication Nov. 5, 1979.

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**Table I.** *Percent of patients answering test questions correctly*

Content of informed consent	Percent of patients answering correctly	
	At 2 hr	At 3 mo
Action of hydrochlorothiazide	92	82
Action of propranolol	77	38
Side effects (wheezing, slow pulse)	28	4
Repeated blood testing	85	73
Repeated electrocardiograms	74	83
Duration of trial	64	65
Freedom to withdraw	77	61
Receive best possible treatment	95	100
Meaning of double-blind	64	46
Average percent correct answers	71.6	61.2

operative Study comparing the relative antihypertensive effectiveness of the thiazide diuretic hydrochlorothiazide and the beta adrenergic blocking drug propranolol. All patients were men with prerandomization diastolic blood pressures averaging between 95 and 114 mm Hg. Of the 39 patients 38 were black; the other was white. The age distribution was as follows: 9 were under 40 yr of age, 11 were between 40 and 49, 16 were between 50 and 59, and 3 were 60 or over. Twenty-seven were employed full-time, most in blue collar occupations; 2 others were self-employed, 2 were unemployed, and 8 were retired. Some had known of their illness for many years, whereas in others it had been only recently diagnosed. Some had received therapy sporadically in the past, although many had never followed any drug regimen. None had previously participated in a therapeutic trial.

Patients who met the medical criteria for the trial and who indicated that they were likely to have the personal motivation and work schedule flexibility required to adhere to the regimen and follow-up schedules were invited to participate in the study. Acceptable patients were asked to enter the trial by the clinic nurse and were given the informed consent statement (Appendix I). The patients then retired to the waiting room

where they were given as much time as they wished to read and digest the contents of the form, usually 10 to 15 min. They were then asked if they had any questions concerning the trial. The information therefore was conveyed to the patients almost entirely by the consent statement. In consenting patients the form was then signed by the patient and the physician and by the clinic nurse or secretary as a witness.

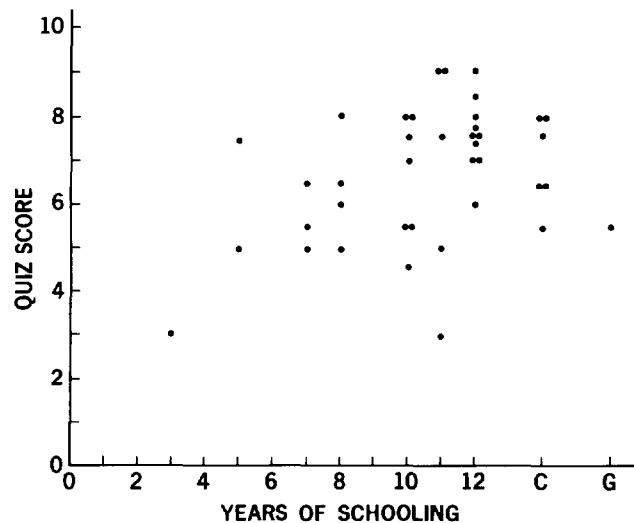
After enrollment the patient was interviewed to obtain a general profile summarizing level of education, prior history of illness, family and employment status, expectations connected with the potential impact of the hypertension and its treatment on their life styles, and the assessment of the significance to them of the factual information about the illness and the trial (Appendix II). Immediately after the interview each patient completed a 9-question, multiple-choice quiz that covered the material presented during the informed consent process (Appendix III). Thirty-nine persons were included in this initial interview and quiz. The quiz was repeated by 23 of the patients 3 mo following their enrollment.

### Results

A high percentage of patients responded correctly to most of the questions presented in the written quiz. The average of correct answers to the 9 questions asked was 71.6% at 2 hr after exposure to the material contained in the informed consent and was 61.2% after 3 mo (Table I).

A notable difference in the level of awareness of the distinctly different actions of the 2 drugs being used was apparent at the time of entry into the trial and was even more pronounced at the end of 3 mo. Initially 92% of participants knew that the action of hydrochlorothiazide was directed toward removal of salt and water, whereas 77% associated propranolol with a quieting effect on the nerves of the heart. After 3 mo the knowledge of the actions of the 2 drugs was 82% for hydrochlorothiazide and only 38% for propranolol.

When queried about possible side effects 11 (28%) of the 39 participants were aware that both wheezing and a slowing of the pulse are possible side effects to one of the drugs being evaluated. Seventeen others (44%) indicated an



**Fig. 1.** Correlation between quiz scores and years of schooling. On the abscissa C indicates 1 or more years of college, and G indicates same for graduate school.

awareness of one or the other of these potential side effects. Eleven gave a totally incorrect response or no response at all. After 3 mo only one participant recalled both potential side effects, and only 2 of the other 23 quizzed recalled that wheezing might be a side effect, but 14 of the 23 indicated that they were aware of a slowing of the pulse as a possible side effect.

Special tests that were to be performed repeatedly on the patients included blood tests and an electrocardiogram. Initially 85% of the participants indicated awareness of the blood testing and 74% of the electrocardiogram. At 3 mo 73% recalled the blood testing and 83% the electrocardiogram.

On entry into the trial 64% comprehended that the study would last 1 yr, and 77% knew that they were free to withdraw from the study at any time and still be assured of the best possible medical treatment. At 3 mo those percentages were 65% and 61%, respectively. Initially 95% indicated that they expected to receive the best possible treatment while they were enrolled in the trial; at 3 mo it reached 100%.

Initially 64% of the participants demonstrated comprehension of the nature of a double-blind trial. At the end of 3 mo only 46% responded that in a double-blind trial neither the patients

nor the doctors knew which drug was being used on an individual participant.

Of the 39 entering participants only 7 indicated during the profile interview that they would not have participated without having received the associated information, and 2 indicated that they probably would not have. Seven said they probably would have agreed to participate without having been informed, and 23 indicated they definitely would have agreed to participate without the information.

No patterns were discernible that would relate age, family or employment status, evidence of symptoms, or level of education to the extent of recall of information as demonstrated by answers to the quiz questions. There was no correlation between the level of education and the number of correct answers to the question given in the quiz (Fig. 1).

## Discussion

The degree of comprehension and recall of the informational content of the informed consent was better than had been anticipated on the basis of former studies,<sup>1, 2</sup> with 71.6% correct answers to the quiz at 2 hr after the consent procedure and 61.2% 3 mo later. Because the information was relayed to the patient primarily by the informed consent statement with very

little oral instruction, except answers to questions, the printed form appeared to be an effective way of conveying the basic facts of the trial to the patient. Several factors may have contributed to this favorable result. The basic design of the trial was relatively simple and straightforward, involving a comparison of one drug against another. The consent statement was written in a clear and popular style, avoiding technical words and phrases wherever possible. It also was personalized by adapting a convention in which the physician appeared to be addressing the patient directly. The patients were left undisturbed for 15 min to read and consider the material contained in the informed consent. A longer period might have been even more effective inasmuch as Morrow<sup>3</sup> demonstrated that the level of comprehension increased when the patients retained the consent form for several days. Finally by means of careful editing the consent statement was made as brief and concise as possible, covering only two thirds of a printed page. In this regard Epstein and Lasagna<sup>1</sup> found that the level of comprehension varied inversely with the length of the informed consent statement.

The quiz served to emphasize major differences in the level of comprehension of different facets of the material included within the informed consent statement. A 92% correct response to the question regarding the action of the thiazide diuretic, as contrasted with the more limited recall for the action of propranolol, may have been the result of popular knowledge that diuretics are used to rid the body of salt and water in hypertension. It seems possible that information previously obtained may contribute significantly to the assimilation of the material received during the informed consent procedure.

The poor recall of potential side effects is consistent with the theory of individual personal denial of unpleasant realities. A selective memory pattern was demonstrated after 3 mo when most patients recalled that slowing of the pulse could be a side effect, whereas virtually none remembered wheezing as a potential hazard. Because pulse rates are routinely checked during follow-up examination, it is possible that this served as a regular reminder to the patients

of the possibility of bradycardia. The present results are consistent with those of Robinson and Merav<sup>4</sup> in their evaluation of the recall of informed consent of patients after 4 to 6 mo following cardiac surgery. They found that the poorest recall was in the area of potential complications. Schultz et al.<sup>5</sup> found that 52% of patients were "adequately informed" of most of the main features of a trial when tested 2 hr after having provided their informed consent but that fewer than 20% understood the personal benefits and risks that were involved in the anticipated therapies.

The information regarding the duration of the trial and the freedom to withdraw at any time was probably of little relevance in this study insofar as some type of antihypertensive therapy would be a continuing need for all participants throughout their lifetimes and would be provided without charge by the clinic. Patients were assured therefore that their care would extend far beyond the end of the trial.

The reason for the relatively poor comprehension of the nature of a double-blind study was not apparent but may be associated with the fact that the concept has somewhat unfavorable implications. Although participants had definite awareness that 2 different drugs were being evaluated, they may have been reluctant to accept the fact that the medical personnel did not have direct knowledge as to which patients were receiving a particular drug. Double-blinding presents a marked contrast to the traditional patient-physician relationship wherein the physician is regarded as the omniscient authority figure. It is possible that patients may avoid awareness of the altered role of the health care delivered in a clinical trial when it is not congruent with their prior conceptualizations and dependency needs.

A high level of personal trust and dependency was indicated in the individual profiles of 75% of the patient, who stated that they would have been quite willing to participate in the trial without having received the information proffered in the informed consent. This pattern was not attributable to overt evidence of the illness, because only 27% of those agreeable to participation under any condition complained of symptoms that might be associated with hy-

pertension. Thus although informed consent is desired by the patients, the most important factor motivating most of them to give their consent appears to be their confidence and trust in the physician and nurse rather than in their understanding of the information provided in the consent procedure.

It was also evident that the dependency pattern was not related to the level of education attained. In both groups there was a spread in educational achievement from less than an eighth grade education to entrance into college. The absence of a correlation between the level of education and the accuracy of recall was surprising. Although the better educated patients were more articulate in their answers to profile questions, they did not show a generally higher level of comprehension in response to the multiple-choice quiz.

During the profile interviews it was also noted that the great majority of participants personalized the objectives of the treatment associated with the therapeutic trial in terms of their own needs. In response to the general question about the purpose of the treatment, only 3 commented that an intent of the trial was to evaluate the effectiveness of 2 alternative therapies in hypertensive patients. The more frequent replies were that the goal was to "control blood pressure," to "increase life expectancy," and to "decrease fears."

This study clearly indicated that the patients' comprehension of the informed consent is fragmentary; some information is retained by most patients, whereas other material is either not comprehended or is soon forgotten. It may be useful therefore to routinely quiz the early entries into a clinical trial to determine the aspects of the study that are poorly understood. The latter information could then be given more emphasis in dealing with later entries, either by verbal reinforcement or by rewriting the consent form.

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### Appendix I. Comparison of propranolol with hydrochlorothiazide for the step-1 treatment of hypertension consent form

We are asking you to take part in an approved study that will compare 2 drugs for treating high blood pressure. Both drugs are widely used to lower blood pressure, but we would like to check them very carefully.

One of the medicines is called hydrochlorothiazide. This is a standard "water pill" that has been used for many years for treating high blood pressure. It helps your kidneys to get rid of both salt and water.

The other medicine is propranolol. It is also used by doctors all over the world to treat high blood pressure. Propranolol has a calming effect on the nerves that raise blood pressure. Some doctors feel that propranolol is a better treatment than hydrochlorothiazide. Others disagree. Our study should help to settle this question.

You will receive one of these medicines "double blind." This means that neither you nor your nurse and doctor will know which medicine it is. You also will receive an inactive tablet for short periods to see how your blood pressure does without active medicine.

If your blood pressure is well controlled we will continue the treatment for 1 year. If it is not, we will take you out of the study and treat your high blood pressure with other medicines until your blood pressure is controlled. After the study is over we will be glad to continue to treat your high blood pressure if you wish us to do so.

Besides measuring your blood pressure and your pulse, we will be doing other tests from time to time. We will draw blood samples every few months. At these times you will need to come in without breakfast. You will then receive an injection of a standard medicine that will make you pass more urine for a few hours. Also chest x-rays and special EKGs will be done. You will have your eyes examined several times during the study.

Sometimes drugs for high blood pressure cause minor discomfort or side effects such as feeling faint, slowing of the pulse, wheezing, or shortness of breath. However, these 2 drugs are pretty free of side effects that might make you feel uncomfortable. You

will be examined so closely there is little risk of any serious problems, and your treatment will be changed at once if you develop this kind of a reaction. I would like you to remember that studies like this one help us to improve your treatment and that of other patients like you.

We will be happy to answer any question you may have at any time. If you decide that you don't want to take part in this study (either now or after you have started on the study), you may be sure that you can drop out and still continue to get the best possible treatment for your high blood pressure. However, it may be dangerous to stop your medication suddenly. Therefore we request that you let the clinic know prior to stopping your medication.

### Appendix II. Interview questions on demographic characteristics

1. Age.
  2. Sex.
  3. Race.
  4. Major complications or hospitalizations.
  5. Education completed.
  6. Employment status.
  7. Marital status.
  8. Structure of immediate family.
  9. For how long have you known about your illness?
  10. Describe your illness.
  11. For how long have you been receiving treatment?
  12. What do you expect the treatment will accomplish?
  13. Do you feel that untreated high blood pressure would affect your life style? Your length of life?
  14. What effects do you think that the treatment will have on your life style? Your length of life?
  15. What do you think the treatment is designed to accomplish?
  16. Are you aware of any risks connected with the therapy?
  17. Do you feel that the medical personnel have been completely honest with you?
  18. Have you sought additional information about your illness? If so, from what sources? Were you able to get the additional information?
  19. Did you want the information your physician gave you when you signed the form agreeing to participate in the trial?
  20. Would you have agreed to treatment without having received the accompanying information?
- c. It makes the kidney put out more proteins.
  - d. It causes the kidney to put out more salt and water.
  2. How does the other drug work?
    - a. It quiets the heart.
    - b. It opens up the blood vessels.
    - c. It quiets your nerves.
    - d. It helps your body get rid of salt.
  3. What is meant by a "double-blind" trial?
    - a. The doctor and the patient both know what drug is being used.
    - b. The doctor knows, but the patient does not know what drug is being used.
    - c. The patient knows, but the doctor does not know what drug is being used.
    - d. Neither the doctor nor the patient know.
  4. How long are you supposed to be in this special study?
    - a. One month.
    - b. Three months.
    - c. One year.
    - d. Two years.
  5. What will happen to your medical treatment when the study is finished?
    - a. You will be discharged and have to find care outside the hospital.
    - b. We will continue to treat your hypertension in the best possible way.
    - c. You will be put immediately into another study whether you wish to be or not.
    - d. The study will be repeated.
  6. What special tests will be done while you are in the study? Check only the correct items.
    - a. Electrocardiogram.
    - b. X-ray of the brain.
    - c. Blood tests.
    - d. Radioactive liver scan.
  7. Which of the following side effects could be caused by the drug you are taking?
    - a. Wheezing or shortness of breath.
    - b. Chest pain.
    - c. Impaired hearing.
    - d. Slowing of the pulse.
  8. Are you convinced that you will receive the best available treatment from the medical people who are treating you?
    - a. Yes.
    - b. No.
  9. What would happen if you decide to withdraw from the trial?
    - a. You will be discharged.
    - b. You will be placed in another study.
    - c. You will continue to receive the best possible treatment.
    - d. You will be sent home with medicine to last for 1 year.

(Patients were told that there could be more than one correct answer for some of the questions.)

### Appendix III. Quiz on content of informed consent

1. One of the 2 drugs you may be taking acts on the kidneys. It acts as follows:
  - a. It causes the kidneys to retain salt and water.
  - b. It affects the size of the blood vessels in the kidneys.